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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,175	02/14/2002	Alan M. Peabody	PEA13	7325

7590 08/25/2003

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EXAMINER
DRODGE, JOSEPH W

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 08/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Appl[illegible](s)	
	10/075,175	PEABODY ET AL.	
	Examiner	Art Unit	
	Joseph W. Drodge	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

[redacted]

NON-FINAL REJECTION

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-19, 21-37, 39-42, 44-53 and 55-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peabody et al patent 5,643,201 in view of

Polaschegg patent 6,280,632 (hereafter abbreviated as "P") and Wamsiedler et al patent 5,808,182 (hereafter abbreviated as "W") .

Peabody et al (201) disclose method and apparatus for operating an automated, continuous, peritoneal dialysis system that comprises dialysate preparation component (RO filter 20 and prefilter 10), a fluid circuit for supplying dialysate towards the patient including pump 40 and conduit 41, etc., a flow of spent dialysate to drain (column 10, lines 34-39), inflow line segment (column 7, lines 11-58), dialysate sterilization component including sterilization filter 53 (column 7, lines 55-58), system controller (column 11, lines 2-6) [as in claims 1, 23 and 32], the controller governing filling and draining (column 8, lines 21-64), a dialysate storage vessel 74 or 62 [as in claims 32 and 39], the volume of dialysate accumulated being monitored, see column 7, lines 42-49 [as in claims 8, 29, 32+ and 39+], an outflow line segment 78,84, and as also required by claim 1, a system sterilization component (column 6, lines 65-67).

The claims all differ in requiring means to test the sterilization filter in real time. However, W teaches such testing of a sterilization filter in a dialysis system (hemodialysis), see column 1, line 66-column 2, line 5 and column 5, lines 17-29, etc. as does P in column 2, line 65-column 3, line 8 and column 3, lines 41-49, etc. It would have been obvious to one of ordinary skill in the art to have augmented the Peabody et al system, with such means to test the sterilization filter in real time, as taught by W and P, in order to ensure adequate, safe sterilization of the dialysate that contacts the patient to avoid infection, etc. and to ensure adequate delivery of sufficient volumes of dialysate to the patient.

Regarding claims 5, 32+, 42+ and 51, P teaches a secondary sterilization filter in column 5, line 50 as does W starting at column 4, line 24.

Regarding claims 4-14, 16-19, 24-26 and 35-37, the sterilization testing component operating by supplying pressurized air to the filter being tested and monitoring subsequent changes in pressure, etc. are also taught by W in column 5, line 57-column 6, line 4 and P in column 8, lines 18-22 and 50-59. Such means of testing membrane filters have become well known in the filter testing art.

Regarding claim 57, isolation and preliminary purging of the filter being tested is taught by at least P at column 8, lines 36-39.

Regarding claims 20-22 and 59-61, the control of the timing of supplying sterilizing fluid (formaldehyde) by Peabody et al infers use of a controlled valve.

Regarding claims 30 and 31, see Peabody at column 10, lines 11-15 concerning draining and fill cycles.

Regarding claims 28, 33, 34, 40 and 50, use of a discard line segment is taught by P at column 9, line 61.

Regarding claims 41, 52 and 53, the abstract of P teaches that testing of the sterilization filter is conducted just prior to dialysate delivery to the dialysis equipment and start of its operation.

Regarding claims 47 and 48, calculating and monitoring of amounts of dialysate being delivered to the patient and of spent dialysate being drained are taught by Peabody et al in column 7, lines 49-53, column 7, line 63-column 8, line 3 and column 8, lines 17-28.

Claims 2, 20, 38, 43 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peabody et al patent 5,643,201 in view of Wamsiedler et al patent 5,808,181 as applied to claims 1, 23, 32, 39 and 49 above, and further in view of Faict et al patent 5,925,011 (hereinafter referred to as "F").

Claim 2 requires proportioning of dialysate from multiple sources so as to adjust its osmality, a feature shown by F column 5, lines 5-11, column 1, lines 18-39, column 4, lines 37-46 and column 8, lines 58-61, etc. It would have been further obvious to one of ordinary skill in the art to have also added such proportioning means to the Peabody et al system, as taught by F, so as to adjust the dialysate to improve the dialysis of waste materials of different types and so as to better ensure safety to the patient by ensuring a pH of the dialysate readily tolerated by organs proximate the peritoneal cavity.

Claims 20, 38, 43 and 54 differ in requiring dialysate delivery systems set up in parallel, see parallel pumping means 12 and 14, etc taught by F. It would have also been obvious to have added such parallel delivery system to the Peabody et al system, as taught by F, to insure consistent delivery of dialysate to the patient even in the event of failure of the pump or a clog, etc. occurring in a single delivery system.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Treu et al patent 6,254,567 teaches complex automation of a peritoneal dialysis system with multiple diverse sensors. DuMoluine et al patent 5,827,820 further discusses osmotic adjustment of peritoneal dialysis fluids.

Any inquiry concerning this communication from the examiner should be directed to Joseph W. Drodge at 703-308-0403 between the hours of 8:30 and 5:00 Mondays through Fridays.

JWD

August 20, 2003

JOSEPH DRODGE
PRIMARY EXAMINER